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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/694,293	10/23/2000	Stephen T. Kuehn	S16.12-0101	1653

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EXAMINER

NGUYEN, VI X

ART UNIT PAPER NUMBER

3731

DATE MAILED: 07/07/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

**Office Action Summary**

Application No.

09/694,293

Applicant(s)

KUEHN ET AL.

Examiner

Victor X. Nguyen

Art Unit

3731

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 04 April 2005.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1,3-5,7,10-13 and 30-33 is/are pending in the application.
- 4a) Of the above claim(s) 2,6,8,9,14,16,17,19,21,22,27 and 29 is/are withdrawn from consideration.
- 5) ☒ Claim(s) 18,20,23-26 and 28 is/are allowed.
- 6) ☒ Claim(s) 1,3-5,7,10-13 and 30-33 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_\_
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date \_\_\_\_\_
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: \_\_\_\_\_

## DETAILED ACTION

### *Claim Rejections - 35 USC § 102*

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1,3-5,7,10-13 and 30-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Krueger et al (5,578,076).

Krueger et al disclose in Figs. 1-2, a heart valve fastener (10) having the limitations as recited in claims 1 and 3, including: one pair of arms (16), where arms pivot from one orientation to a gripping position with ends of the paired arms being directed toward each other (at best seen in fig. 2 where the curved segment 74 is capable of being directed toward the curved segment 76. Regarding the intended use of the pair of arms are sized and adapted for fastening two adjacent tissue heart valve leaflets, a recitation of the intended use of the claimed invention must result in a structural difference between the claimed invention and the prior art in order to patentably distinguish the claimed invention from the prior art. If the prior art structure is capable of performing the intended use, then it meets the claim. In the instant case, the arms of Krueger would have been capable of performing the use as claimed. In a claim drawn to a process of making, the intended use must result in a manipulative difference as compared to the prior art. See *In re Casey*, 152 USPQ 235 (CCPA 1967) and *In re Otto*, 136 USPQ 458, 459 (CCPA 1963). As to claims 4-5,7,10-13, a system further has a catheter or a trocar (see col. 2, lines 63-67, col. 3, line 1 and col. 4, lines 14-18) that is inherently capable for deployment into a human heart, where the paired arms (16) extend toward each other when the fastener is in a gripping

Art Unit: 3731

position, and where the arms flex to a low profile position to fit within the catheter, where the fastener further has a shaft (60) that is releasably holding the fastener of the shaft

Regarding claims 30-33, Krueger et al disclose in Fig. 18, where a fastening member comprises a cap (370) and a gripper (366) comprises a plurality of arms (374) from a pivot (372), where each arm has a spike (376), and where the cap comprises a locking mechanism to lock the gripper in a lock position (see col. 6, lines 41-51), and where the fastener further has a flexible rod (125) which has a disengaging mechanism (fig. 5) which permits the rod to releasably holding the cap.

#### **Allowable Subject Matter**

2. Claims 18,20,23-26 and 28 are allowed.

The following is a statement of reasons for allowance: None of the prior art of record, alone or in combination, discloses or suggests where a heart valve repair instrument comprising a cap that is located distal to the pivot and the pivot is located distal to a shaft, where a flexible rod connects to the cap to provide for movement of the cap relative to the pivot of the gripper and the shaft by pulling the flexible rod, where the cap has an opening that can be positioned over the pivot to lock the arms in a closed position.

As allowable subject matter has been indicated, applicant's reply must either comply with all formal requirements or specifically traverse each requirement not complied with. See 37 CFR 1.111(b) and MPEP § 707.07(a).

#### ***Response to Arguments***

Art Unit: 3731

3. Applicant's arguments filed 4/4/2005 have been fully considered but they are not persuasive. Applicant states that examiner should not have been withdrawn claims 4-5,7,10-13,18,20,23-26,28 and 33. In response to this argument, examiner asserts that the replacement drawing of figure 15g includes claims 4-5,7,10-13,18,20,23-26,28 and 33 for the purposes of examination.

In response to applicant's argument that Krueger "does not suggest a pair of arms being adapted for fastening two adjacent tissue heart valve leaflets" (a functional limitation): It is noted that figure 1 of Krueger can be clearly defined element 16 having a pair of arms. Thus, a reference needs not show the structure of the recitation in order to meet the claim language but rather the reference needs only be capable of being used with such structure. Accordingly, the above noted reference is still considered to read on the claimed limitations of the claims noted.

In response to Applicant's argument, the recitation that "A heart valve leaflet fastener" has not been given patentable weight because the recitation occurs in the preamble. A preamble is generally not accorded any patentable weight where it merely recites the purpose of a process or the intended use of a structure, and where the body of the claim does not depend on the preamble for completeness but, instead, the process steps or structural limitations are able to stand alone. See *In re Hirao*, 535 F.2d 67, 190 USPQ 15 (CCPA 1976) and *Kropa v. Robie*, 187 F.2d 150, 152, 88 USPQ 478, 481 (CCPA 1951).

#### ***Conclusion***

4. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

U.S. Pat. No. 4,605,002 to Rebuffat

U.S. Pat. No. 6,695,866 to Kuehn

Art Unit: 3731

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Victor X. Nguyen whose telephone number is (571) 272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anh Tuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Victor X Nguyen  
Examiner  
Art Unit 3731

Vn Vn  
6/30/2005



**JULIAN W. WOO**  
**PRIMARY EXAMINER**